COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

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SUPERIOR COURT
CIVIL ACTION
NO. 03-5028-B

KARLA SAWYER & others[1]

vs.

INDEVUS PHARMACEUTICALS, INC.[2]

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

The plaintiffs brought this action on December 11, 2003, against Indevus Pharmaceuticals, Inc. ("Indevus") seeking damages for alleged injuries caused by their use of the drug "Redux" (dexfenfluramine), a prescription drug used to manage obesity. The plaintiffs allege that Redux caused them to suffer Valvular Heart Disease (VHD). Counts I & II seek damages for breach of warranty, Count III for negligence, Count IV for negligent misrepresentation, and Count V for violating G.L. c. 93A.

Pursuant to Mass. R. Civ. P. 56(c), Indevus now moves for summary judgment on the ground that the plaintiffs' claims are barred by the relevant three and four year statutes of

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[1] Linda Paul, Jeannie Rose, & Joyce Palomba

[2] F/k/a/ Interneuron Pharmaceuticals, Inc.

limitations.[3] The plaintiffs oppose the motion, arguing that the statutes of limitations were tolled until they were diagnosed with VHD in late 2001/2002. For the reasons to follow, the defendant's motion will be **DENIED**.

BACKGROUND

This case is but one of thousands of similar cases nationwide arising out of heart damage allegedly suffered as a result of ingesting Redux (dexfenfluramine) and Pondimin[4] (fenfluramine) (the "Diet Drugs" or "Diet Drug"). The following history of the Diet Drugs, related litigation (the "Diet Drug Litigation"), and the circumstances of this case is provided in as much detail as is necessary and relevant to deciding the defendant's motion.[5]

1. Redux Hits the Market

Indevus[6] licensed the right to develop and promote Redux in the Unites States from Les Laboratories Servier S.A., a French company. In 1994, Wyeth,[7] the company marketing and promoting the related Fen-Phen combination, acquired Indevus' co-licensee. As part of the arrangement, Wyeth assumed responsibilities for developing and promoting Redux in the United

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[3] Counts I, II, III & IV are governed by three year statutes of limitations. See G.L. c. 260, § 2A; G.L. c. 106, § 2-318. Count V is governed by a four year statute of limitations. G.L. c. 260, § 5A.

[4] Pondimin was commonly prescribed in combination with Phentermine. The combination is commonly referred to as "Fen-Phen." Phentermine is not part of the Diet Drug litigation.

[5] The Multi District Litigation (MDL) Court which approved a related nationwide settlement provided an extremely thorough and detailed history of the Diet Drug Litigation which can be found at *Brown v. American Home Prods. Corp. (In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.)*, Nos. MDL 1203, 99-20593, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000) (Bechtle, J.).

[6] This court will refer to Interneuron Pharmaceuticals, Inc. as "Indevus" throughout this opinion.

[7] At the time Wyeth was American Home Products, Corp.

States and the two companies entered into a co-promotional agreement. Indevus remained involved in its marketing, promotion and distribution, and sponsored the application for FDA approval which was granted in mid-1996. Production and robust sales followed shortly thereafter. *In re Diet Drugs*, 369 F.3d 293, 298 (3rd Cir. 2004) (by September 15, 1997 over four million people had taken Pondimin and two million had taken Redux).

2. Valvular Heart Disease & the Diet Drugs

Valvular Heart Disease manifests itself symptomatically as heart valve regurgitation, where the affected heart valve improperly permits blood to leak (or "regurgitate") back into the chamber from which it was pumped. The Diet Drugs cause regurgitation by producing plaques that stick to the valve structure causing lesions thereon. Those lesions affect the normal function of the valve, ultimately causing regurgitation.

The regurgitation, if severe enough, can be detected through auscultation (listening to the heart through a stethoscope). However, even significant regurgitation may be silent on auscultation. On the other hand, the "gold standard" for detecting even minimal amounts of regurgitation is an echocardiogram. An echocardiogram is a noninvasive procedure whereby doctors use ultrasonic technology to obtain live pictures of the heart, much like the procedure used to view a fetus in the womb. Thus, regurgitation that may go undetected on auscultation would be detectable in an echocardiogram.

3. Signs of Trouble Surface: Diet Drugs Withdrawn from the Market

On July 8, 1997, doctors at the Mayo Clinic reported a possible association between the use of the Diet Drugs and VHD. The Mayo Clinic findings were issued in a press release and

were later formally published in the New England Journal of Medicine in late August of 1997. As part of the press release, the Mayo Clinic included a section entitled "Information and Recommendations for People Taking Fenfluramine and Phentermine" which stated, *inter alia*:

> If you are using fenfluramine and phentermine (fen-phen):
>
> Contact your primary physician. Discuss these findings with your physician, and then ask him or her to help you weigh the benefits and risks of therapy.
>
> Remain calm. More comprehensive study is needed to make a definitive statement about the association between [VHD] and [fen-phen].

Also on July 8, 1997, the FDA issued a public health advisory, and sent letters to 700,000 physicians requesting information about patients using the Diet Drugs. Based on the information received in response to that request, Redux and Pondimin were pulled from the market on September 15, 1997.

Wyeth promptly sent a "Dear Health Care Provider" letter on September 15, which characterized the association between VHD and the Diet Drugs as "preliminary," "difficult to evaluate," and "not derived from a thorough clinical study." The letter explained the decision to withdraw the drugs as "the most prudent course of action," and noted that "patients will be advised to contact their physicians." The letter did not indicate that the physician should consider or perform any specific tests or examinations. At the same time, Wyeth issued a press release and purchased advertisements in newspapers across the country. The advertisements were entitled: "An Important Message To Patients Who Have Used Pondimin® Or Redux™" and described a possible link between the Diet Drugs and VHD. Both the press release and the advertisement concluded by stating, "patients who have used either [Pondimin or Redux] should contact their physicians."

At the time of the withdrawal, neither the pharmaceutical companies nor the government notified Diet Drug users that an echocardiogram was necessary to diagnose or discover VHD. Diet Drug users were told only to consult their physicians.

4. Media Coverage & Public Notice

There can be little doubt that the potential link between the Diet Drugs and heart disease and the Diet Drug withdrawal was one of the biggest news stories of 1997. Local and national media outlets extensively covered the July 8 announcement, including newspapers and television newscasts. For example, *The New York Times* and *USA Today* both ran four-page articles bearing the headlines "2 Popular Diet Pills Linked to Problems with Heart Valves" and "Diet Drug Patients Get Heart Warning" respectively. Gina Kolata, 2 popular Diet Pills Linked to Problems with Heart Valves, N.Y. Times, July 9, 1997, at A1; Nancy Hellmich, Diet Drug Patients Get Heart Warning, USA Today, July 9, 1997, at 1A. Local and Regional papers across the nation and New England, such as *The Boston Herald* and *The Boston Globe*, featured front-page reports on the Mayo Clinic announcement. See, e.g., Michael Lasalandra, Study Links Diet Pill Fen-Phen to Heart Problems, Boston Herald, July 9, 1997, at 1; Dolores Kong, Blend of Diet Drugs Tied to Heart Disease, Boston Globe, July 9, 1997, at A1.

The September 15 withdrawal of the Diet Drugs received similar headline coverage. Both Tom Brokaw on "NBC Nightly News" and Dan Rather on "CBS Evening News" led the evening newscasts with stories covering the withdrawal. NBC Nightly News (NBC Television Broadcast, September 15, 1997); CBS Evening News (CBS Television Broadcast, September 15, 1997). *The New York Times* and the *Washington Post* also ran front-page headline stories of the

withdrawal. Gina Kolata, 2 Top Diet Drugs Are Recalled Amid Reports of Heart Defects, N.Y. Times, September 16, 1997, at A1; John Schwartz, 2 Diet Drugs Are Pulled off Market, Washington Post, September 16, 1997, at A1. Similar stories saturated local and regional newspapers. E.g., Norma Wagner, Drug Seller Pulls Its Diet Pills; FDA Says Review Suggests Drugs Are Not Heart-Healthy, Salt Lake Tribune, September 16, 1997, at A1; Richard A. Knox, 2 Diet Drugs Pulled As Fears Grow, Boston Globe, September 16, 1997, at A1; Michael Lasalandra, Docs Urge Former Fen/Phen Takers to Get Thorough Checkups, Boston Herald, September 17, 1997, at 7.

In short, it was virtually impossible to escape the widespread coverage of the issue. This court recognizes that a reasonable Pondimin or Redux user should have, at minimum, been aware of the controversy and the possibility that he or she was at risk for heart disease. What requires closer attention, however, is the actual content of that coverage and the precise message, if any, a Diet Drug user should have taken therefrom.

The preliminary media reports in July of 1997 indicated that researchers had uncovered a potential link between the Diet Drugs and VHD. For example, the initial press release from the Mayo Clinic described the health risks possibly associated with the use of Diet Drugs, and newspaper and news broadcast coverage of the report provided details of the Mayo Clinic's findings, which included abnormal echocardiogram findings. Subsequent reports focused on the potential link. See, e.g., Chris Tomlinson, Diet-Drug Mix May be Deadly FDA Warns; "Fen-Phen" Linked to Heart, Lung Damage, San Francisco Examiner, July 9, 1997, at A1; Terence Monmaney, Fen-Phen May Cause Damage to Heart Valves, Los Angeles Times, July 9, 1997, at A1. Similarly, a New York news broadcast warned: "If you or someone you know are taking

Fen-Phen to lose weight, this is a story you must hear. Researchers say the pills could put your health at risk." 2 News This Morning (WCBS-TV Television Broadcast, July 9, 1997). The media also began to report that Diet Drug users should consult their physicians. An article in *The Boston Globe*, for example, urged users to "see a doctor and get a physical exam," as the Diet Drugs "were pulled from the market because extended use for six months or more ha[d] been linked to potentially deadly heart valve damage." Exams Urged For All Users of Fen-Phen, Redux, Boston Globe, November 14, 1997, at A3. See also Nancy McVicar and Glenn Singer, Study: Diet Drugs May be Associated With Heart Disease "Fen-Phen" Could Damage Valves, Doctors Conclude, Sun-Sentinel, July 9, 1997, at 1A (providing readers with the typical symptoms of heart valve problems and recommending that patients using the medication "[d]iscuss the findings with [their] doctor[s]").

The media attention surrounding the Diet Drug withdrawal in September of 1997 was accompanied by widespread warnings to stop taking them and to consult a physician. The Wyeth, Indevus and FDA press releases discussed abnormal echocardiogram findings in the patients, but did not advise the users to have an echocardiogram performed; rather, the releases uniformly advised Diet Drug users to "contact their doctors." See, e.g., Press Release, Food and Drug Administration, FDA Announces Withdrawal of Fenfluramine and Dexfenfluramine (September 15, 1997) (specifically urging users to stop taking the drugs and to contact their physicians). Similarly, newspapers nationwide conveyed the same warnings and advice. E.g., Tara Meyer, Diet Drug Users Are Told to See Doctors; Advice Goes for Those Feeling Fine, Boston Herald, November 14, 1997, at 3; Exams Urged for All Users of Fen-Phen, Redux, Boston Globe, November 14, 1997, at A3; Marlene Cimons, 2 Diet Drugs Tied to Heart

Problems Taken Off the Market, Los Angeles Times, September 16, 1997, at A1 (discussing the removal and advising users to "immediately stop taking the pills . . . . [and] [s]ee a doctor"); Lauran Neergaard, Recall Spurs Dieters to Seek Heart Test, Buffalo News, September 25, 1997, at A8 ("immediately stop taking the drugs and see a doctor").

As the general public was receiving information concerning Diet Drugs and VHD, so too was the medical community.[8] The pharmaceutical companies themselves advised physicians of the Mayo clinic findings and FDA data. Physicians were notified that Diet Drug users had been advised to contact them. Neither Diet Drug users or their treating physicians, however, were advised that an echocardiogram should have been performed. To the contrary, the government, authoritative medical associations and the Diet Drug manufacturers themselves uniformly advised that standard examinations should be performed to determine whether further echocardiogram testing was called for. For example, the Department of Health and Human Services recommended to physicians that they take a medical history of Diet Drug patients and perform a cardiac exam–only performing an echocardiogram if the initial exam indicated VHD. The advice from all of the medical and scientific communities to physicians in this regard (as it appears in the record presently before the court) was uniform–order an echocardiogram only when cardiac examination/auscultation indicates detectable VHD. Indeed, Wyeth sent a letter to Secretary of Heath and Human Services, Donna Shalala, discouraging her from recommending routine echocardiograms for Diet Drug users. Specifically, Wyeth advised her that "such a

[8] As will be discussed below, the relevance of these notices to the current motion is dubious. None of the plaintiffs were physicians and should not reasonably be expected to have known or discovered (let alone, understood) the contents of technical bulletins issued to the medical community. In any event, as noted, it appears undisputed that the protocol for examining asymptomatic Diet Drug users did not include echocardiogram examination.

recommendation would be inconsistent with a recommendation recently issued by the American College of Cardiology as well as with what we understand to be the weight of expert opinion in the cardiology community."

In short, when the drugs were removed from the market in September of 1997 and thereafter, Diet Drug users were notified of the potential association between the Diet Drugs and heart disease and were directed to consult with their physicians. Importantly, however, neither Diet Drug users nor their physicians were advised that an echocardiogram should be performed as a matter of course. Despite the eight hundred and sixty one exhibits offered by Indevus in support of its motion–most of which are media reports, it has not brought to this court's attention a single public report that would have put Diet Drug users on notice that an echocardiogram was necessary to diagnose Diet Drug induced heart disease.[9]

5. The Lawsuits Begin

Almost immediately after the Diet Drugs were withdrawn from the market, thousands of lawsuits were filed against Wyeth and Indevus. *In re Diet Drugs*, 2004 WL 1152824 at *3 (eighteen thousand lawsuits filed; one hundred putative class actions). Litigation was consolidated in state courts throughout the nation, including Massachusetts. In the federal courts, the Judicial Panel on Multidistrict Litigation (MDL) created a multidistrict litigation docket in the United States District for the Eastern District of Pennsylvania in December, 1997, presided

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[9] Judge Bechtle characterized the publicity surrounding the withdrawal as an "unprecedented amount of publicity which effectively warned Diet Drug users that they may have developed valvular lesions which could be detected through non-invasive echocardiograms." *Brown*, 2000 WL 1222042, at *18. With due respect for that Court's characterization, Indevus has not directed this court to anything in the record of *this* case that would lead to the same conclusion.

over by Judge Louis Bechtle.

Negotiations between Wyeth and putative class members commenced, and in November of 1999, a tentative global settlement agreement (the "Agreement") was reached and conditionally approved by the MDL court. The Agreement subdivides the class, defined as all person in the U.S. who ingested Redux or Pondimin, based on the length of use of the Diet Drugs and severity of injury, if any, diagnosed before September 30, 1999. During the course of settlement negotiations, each subclass was represented by independent counsel to advance and protect its interests. There was, however, no subclass with independent representation defined as asymptomatic Diet Drug users as of September 30, 1999.

Indevus was/is not a party to the Agreement.

6. The MDL Court Approves A Nationwide Class Action Settlement with Wyeth

Wyeth and the class representatives moved jointly to approve the settlement. On August 28, 2000, Judge Bechtle certified the class and approved the Agreement. *Brown v. American Home Prods. Corp. (In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.)*, Nos. MDL 1203, 99-20593, 2000 WL 1222042, Memorandum and Pretrial Order No. 1415, (E.D. Pa. Aug. 28, 2000) (hereinafter "*Brown*"). The Agreement became effective on January 3, 2002, the date of Final Judicial Approval.

A. The Agreement

The Agreement was designed to shield Wyeth against excessive liability while simultaneously preserving class members' rights to compensation for their injuries–either through the newly created settlement fund or through claims in the tort system. See generally, *In*

re Diet Drugs, 369 F.3d at 296-300. Under the terms of the Agreement, Wyeth agreed to pay up to approximately $3.75 billion into a settlement trust to provide benefits to class members in exchange for a release of all settled claims. Importantly, the Agreement was structured so as to eliminate an 'all or nothing' choice for class members with respect to participation in the settlement; the Agreement provided several avenues through which class members could "opt-out" and pursue their claims in the tort system, even after the Agreement became effective.

The opt-out provisions worked as follows. All class members could exercise an "initial opt-out right," through which they could remove themselves entirely from the class and prosecute their claims without effect from the Agreement. The deadline to exercise this right was March 30, 2000. Those who chose not to exercise the initial opt-out are bound by the terms of the Agreement. The Agreement provides for a screening period, during which class members could receive an echocardiogram.[10] Importantly, the Agreement protects class members' rights to pursue claims in the tort system if they discover their heart conditions during the screening period–a time when their claims might otherwise be barred by local statutes of limitations. If diagnosed with VHD during the screening period, class members could elect either to receive benefits from the settlement fund or to exercise an "intermediate" or "back-end" opt-out through which they could pursue their claims in the tort system.

For a class member diagnosed with "mild mitral regurgitation"[11] during the screening period, settlement benefits are available in the event that the condition progresses to serious

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[10] The Screening Period commenced on January 3, 2002, and ran for twelve months terminating on January 3, 2003. It could be extended for an additional six months for cause shown.

[11] A "completely asymptomatic condition" requiring no treatment. *Brown*, 2000 WL 1222042, at *10.

levels by the year 2015. In the alternative, he/she may exercise the "back-end opt-out." Under the "back-end opt-out," class members may not pursue claims for consumer fraud, exemplary, punitive, or multiple damages and Wyeth cannot assert, *inter alia*, any statute of limitations defense.

For class members diagnosed with "FDA Positive"[12] levels of VHD during the screening period, the member has a similar choice of electing benefits from the settlement or opting out to pursue claims in the tort system. Under the "intermediate opt-out," class members similarly are entitled only to pursue compensatory damages and Wyeth is precluded from asserting a statute of limitations defense.

In short, the Agreement was structured in such a way as to remove statutes of limitations as an obstacle to recovering compensatory damages for class members who either (a) discover their conditions before January 3, 2003 but after the applicable state statute of limitations may have expired (like the plaintiffs), or (b) have conditions which progress over time to a compensable level.

The Agreement was also designed to limit its preclusive effects against both parties, except as contemplated by the parties and explicitly stated in the Agreement itself. See *In re Diet Drugs*, 369 F.3d at 308-310. The Agreement contained several provisions prohibiting the parties from using the Agreement or statements and/or proceedings related to its negotiation and approval in contexts other than its execution and enforcement. Notably, Section VIII.F.3 of the Agreement provides:

> The Parties to the Settlement ... shall not seek to introduce and/or offer the terms of

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[12] The clinical term characterizing "moderate" or "severe" levels of mitral valve regurgitation.

> the Settlement Agreement, any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Settlement Agreement, any statements in the notice documents appended to this Settlement Agreement, stipulations, agreements, or admissions made or entered into in connection with the fairness hearing or *any finding of fact or conclusion of law made by the Trial Court*, or otherwise rely on the terms of this Settlement, in any judicial proceeding, except insofar as it is necessary to enforce the terms of the Settlement. (emphasis added).

Section VIII.F.4 provides:

> Neither this Agreement nor ... any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this agreement, is intended to be or shall be construed as or deemed to be evidence of . . . an admission by . . . members of the settlement class of any lack of merit in their claims, and *no such statement, transaction, or proceeding shall be admissible in evidence for any such purpose except for purposes of obtaining approval of this Settlement Agreement* in this or any other proceeding. (emphasis added).

B. The Settlement Approval Process - Notice

As part of the settlement approval process, an extensive notice program for prospective class members was initiated.[13] The notice program had two parts. The first was designed to inform putative class members of the health risks associated with the Diet Drugs, class members' legal rights, and that there was a proposed settlement. This part of the notice program was implemented through large scale media advertising, including television and newspaper commercials as well as through dissemination of materials to pharmacies and health care providers. This first part of the notice program also directed Diet Drug users to obtain an official "notice package"–the second part of the notice program.

The "notice package" was sent directly to more than 200,000 known Diet Drug users and could be obtained by other Diet Drug users through an advertised website and toll free phone

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[13] Judge Bechtle described it as "an elaborate and extensive plan of notice." *Brown*, 2000 WL 1222042, at *35.

number. The "notice package" contained two components. The first, which was approved by the MDL Court, was a brochure that provided "the background of the Diet Drug Litigation and the Settlement Agreement in a way that would be read and understood by all class members. . . it was written in plain English and contained a number of pictures, charts and graphs." *Brown*, 2000 WL 1222042, at *37. The brochure did not inform Diet Drug users of the possibility that non-settling parties could use the negotiations, the hearings, or the Agreement against class members in the future.

The second component of the "notice package" was the Official Court Notice, which "contained a detailed description of the Settlement Agreement, typeset in the manner traditionally used to provide legal notice." *Id.* Under the section entitled, "Definition of 'Released Parties'–By participating in this settlement agreement, who am I agreeing to release from existing or future lawsuits regarding my use of Pondimin and/or Redux?", Indevus is specifically listed as a "non-released" party. In addition, the notice provides: **"The rights of Class Members to pursue legal claims against Non-Settling Defendants is not affected by this Settlement Agreement..."** (Emphasis added).

C. MDL Court Approval of the Settlement Agreement

The MDL Court held a comprehensive evidentiary fairness hearing to aid in determining whether to certify the class and approve the settlement under Fed. R. Civ. P. 23. In order to approve the Agreement, the Court had to find that it sufficiently protected the rights of all putative class members–*i.e.*, that there were no disabling conflicts of interest between subgroups within the class. Specifically, it was critical that there was no "futures" problem as identified by

the United States Supreme Court in *Amchem Products., Inc. v. Windsor*, 521 U.S. 591 (1997), such as a conflict between those class members currently injured and those whose injuries may be latent. *Brown*, 2000 WL 1222042 at *45-49. The "objectors" to the settlement were afforded "a full and fair opportunity to offer all of the evidence that they wished to tender to the court concerning" the proposed Agreement. *Id.* at *6. There were fewer than thirty objectors, none of whom presented any medical or scientific evidence to counter the proponents' latency claims. *Id.*[14]

Judge Bechtle noted that all of the literature and medical testimony before him indicated that valvular lesions (the root cause of Diet Drug induced VHD/regurgitation) are not latent, that is, they occur at or shortly after the time of Diet Drug ingestion. *Brown*, 2000 WL 1222042 at *18 & 46-47. The Court specifically held that Diet Drug induced VHD is clinically detectable "shortly after" cessation of Diet Drug use. *Id.* at *46. However, the Court also noted that it was "generally accepted that VHD . . . is potentially progressive." *Id.* at *10.

In light of these findings, Judge Bechtle first acknowledged the substantial statute of limitations obstacle that could face many potential class members who tried to pursue their claims in state courts. The Court specifically noted that it was "beneficial for diet drug recipients to obtain appropriate legal protections such that they have a viable claim for relief when, as, and if, they discover they have either FDA positive levels of regurgitation or that they have serious VHD" because of "vagaries in the law governing recovery for potentially progressive injuries" and the potentially preclusive effects those vagaries might have on "damage claims of individuals

[14] The plaintiffs in this case present the affidavit of Dr. James Oury, who avers that he informed class counsel in *Brown* of his opinion that VHD was latent but that, for reasons unknown to him, he was not called to testify at the fairness hearing.

who are not presently suffering from serious diet-drug induced VHD." *Id.* at *18-*19. After the Court's analysis, it concluded that the Agreement provided sufficient protection for all class members' rights.

First, all class members screened by echocardiogram within the applicable screening period would know whether they had been affected by the Diet Drugs, because, as the Court held, lesions were not latent and were immediately detectable by an echocardiogram. Therefore, there was no risk of a subclass being shut-out from settlement benefits because of a latent onset of valvular lesions. Moreover, for those who were asymptomatic or whose conditions worsened over time, their rights were protected by the intermediate and back-end opt-out provisions as well as provisions entitling them to enhanced benefits when and if symptoms worsened.

That the Court and the Agreement anticipated latent or progressive symptoms is manifest in the Agreement itself. Class members merely needed to demonstrate a relatively mild level of VHD by January 3, 2003, and had until 2015 to assert their claims–whenever their conditions progressed to compensable levels. Moreover, subclasses 1(a) and 1(b) included Diet Drug users who were not diagnosed as having FDA positive levels of VHD by September 30, 1999. Both subclasses were entitled to benefits under the Agreement when and if their conditions reached a certain severity. It is clear, then, that the Agreement anticipated that regurgitation/VHD may be either symptomatically latent or progressive in nature. Indeed, class counsel's Memorandum in Support of Final Settlement Approval, which is part of the record in the current case, indicates as much. In arguing that there was no futures problem, class counsel stated:

> The current settlement affords the required option by way of the intermediate and back-end opt-out provisions. Moreover, the settlement goes a step further by providing medical monitoring to inform persons of their injury status. Those class

> members who pass through the medical monitoring program and learn they have a clinically significant injury as defined by the FDA criteria will have the right to opt out of the settlement and take their claims to court. If, during the ensuing fifteen years, a previously uncompensated class member has an injury that progresses to a higher level of valvulopathy, the individual has one more chance to opt out and pursue individual litigation if he or she does not like the settlement matrix benefits.

Thus, agreeing with class counsel and finding that the Agreement adequately protected against a fatal *Amchem*-like "futures" problem, Judge Bechtle approved the Agreement.

7. The Plaintiffs

There are four plaintiffs in the current action: Karla Sawyer, Linda Paul, Jeannie Rose, and Joyce Palomba. Sawyer, Paul and Rose all ingested Redux in 1996 and 1997. Palomba ingested Redux in 1996. In late 1997, Sawyer's physician discontinued her use of Rexux and referred her for an echocardiogram. She was told that the echocardiogram was normal and that she had nothing to worry about. Each year from 1996 through 2002, the plaintiffs visited physicians for yearly physicals, regular checkups, and treatment of minor ailments. All of their physicians examined their hearts through auscultation. None of the plaintiffs was told that those examinations were irregular, that there was any indication of a heart murmur or other cardiac abnormality, or that she had any other problem associated with Redux. They all felt in good health and had no indications of heart problems. During that time, neither Paul, Rose nor Palomba was advised to have an echocardiogram. If so advised, they all would have consented to the procedure.

In November of 2001 and December, May and June of 2002, Rose, Sawyer, Paul and Palomba respectively, had echocardiograms performed. It was at these times that the plaintiffs first learned they had VHD.

8. Procedural and Circumstantial Posture of This Case

This case was brought solely against Indevus, a Delaware Corporation with its principal place of business in Lexington, Massachusetts. Subsequent to the Agreement being approved, many suits have been filed across the Nation in state courts against Wyeth under the Intermediate and/or Back-end opt-out provisions. Many of these plaintiffs apparently believe that state courts provide a more favorable forum for their claims, and have allegedly attempted to avoid removal to the MDL Court by joining non-diverse defendants alongside Wyeth, thus defeating diversity jurisdiction in the federal courts. Wyeth maintains that it has successfully overcome many such attempts by asserting the doctrine of fraudulent joinder.

Under the doctrine of fraudulent joinder, a plaintiff may not prevent removal by making a claim against a non-diverse defendant when there is no reasonable basis in fact or colorable ground supporting that claim. Thus, where claims against the non-diverse defendant are barred by the statute of limitations, the federal court's jurisdiction over claims against the diverse defendant will not cease. In related Diet Drug Litigation, the MDL Court on several occasions has retained jurisdiction over cases where the state statute of limitations would preclude claims against fraudulently joined non-diverse physicians or other defendants. See, e.g., *French v. Wyeth*, MDL No. 1203, Civil Action No. 03-20206 (E.D. Pa. Feb. 16, 2004); *Alexander v. Wyeth*, MDL No. 1203, Civil Action No. 03-20206 (E.D. Pa. Jan. 29, 2004); *Ferrell v. Wyeth*, MDL No. 1203, Civil Action No. 03-20094 (E.D. Pa. Sept. 5, 2003).

Plaintiffs from around the country are allegedly now testing this strategy in Massachusetts. See, e.g., *Anderson v. Indevus Pharmaceuticals, Inc.*, Civil No. 04-911

(Middlesex Sup. Ct). Wyeth has removed those cases, in which it is a named defendant, to the United States District Court for the District of Massachusetts, and will assert that the plaintiffs have fraudulently joined Indevus based on the expiration of the relevant statutes of limitations and that the cases should be transferred to the MDL Court. The current plaintiffs have brought this case in the Massachusetts Superior Court, so that they can obtain a ruling from a Massachusetts Court on whether their claims against Indevus are barred by the Massachusetts statutes of limitations and therefore whether the removed cases should be remanded to the Superior Court.

This court recognizes the larger implications of the following decision and its possible relevance to the many[15] additional cases waiting in the balance. That circumstance will play no role in the following decision. The plaintiffs and the defendant have a right, which this court will fully honor, to have this motion decided on the merits.

DISCUSSION

1. Issues for Summary Judgment

Indevus argues that the applicable statutes of limitations bar the plaintiffs' claims. Specifically, it argues that the plaintiffs, as a result of the intense media attention on or about September of 1997, were on inquiry notice that they potentially had VHD and, as a matter of law, should have discovered their conditions at or about that time. The plaintiffs argue that the discovery rule saves their claims, because they did not know, nor should they have been expected to know, that they had VHD until echocardiograms in 2001 and 2002 resulted in positive

[15] Wyeth, who has filed an *amicus* brief, claims that plaintiffs' counsel has indicated its intent to bring cases on behalf of 4,597 plaintiffs–in addition to the already 2,368 Diet Drug plaintiffs with cases pending–if they are successful in defeating the current motion.

diagnoses.

2. Standard

Summary judgment will be granted if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits . . . show that there is no genuine issue as to any material facts and that the moving party is entitled to judgment as a matter of law." Mass. R. Civ. P. 56(c). *Kourouvacilis v. General Motors Corp.*, 410 Mass. 706, 716 (1991). "A plaintiff who invokes the discovery rule by claiming that her delay in filing suit stems from a failure to recognize the cause of her injuries bears the burden of proving both an actual lack of causal knowledge and the objective reasonableness of that lack of knowledge." *Doe v. Creighton*, 439 Mass. 281, 284 (2003); *Lindsey v. Romano*, 427 Mass. 771, 773-74 (1998). This question is "one of fact which in most instances will be decided by the trier of fact." *Riley v. Presnell*, 409 Mass. 239, 240 (1991).

Because the plaintiffs bear the burden of proof on the discovery rule, "to survive the defendant's motion for summary judgment the plaintiff[s] must demonstrate a reasonable expectation of proving that [their] suit was timely filed." *Doe*, 439 Mass. at 284. In determining whether the plaintiffs have met this burden, the court will view the evidence produced and draw all reasonable inferences in a light most favorable to the plaintiffs. *Labonte v. Hutchins & Wheeler*, 424 Mass. 813, 821 (1997).

3. The Discovery Rule in Massachusetts

Where a defendant's conduct causes an undetected injury to the plaintiff, Massachusetts applies the 'discovery rule' to determine "when [the] cause of action accrues and triggers the

beginning of the statutory period." *Mohr v. Commonwealth*, 421 Mass. 147, 156 (1995). "[A]ccrual of the cause of action is held to be in abeyance until the time when a modicum of knowledge [of the injury] supplants ignorance in the mind of the claimant, or may be reasonably imputed to her." *Lijol v. MBTA*, 28 Mass. App. Ct. 926, 928 (1990). The critical date is "when a plaintiff discovers, or any earlier date when she should reasonably have discovered, that she has been harmed or may have been harmed by the defendant's conduct.'" *Mohr*, 421 Mass. at 156, quoting *Bowen v. Eli Lilly & Co.*, 408 Mass. 204, 205 (1990).[16] The test is an objective one: "Only if a *reasonable person in the plaintiff's position* would have been able to discern the harm or the cause of the harm will the cause of action accrue and the limitations period begin to run." *Riley v. Presnell*, 409 Mass. 239, 245 (1991) (emphasis added). Thus, the clock will not start ticking until the plaintiff has "(1) knowledge *or sufficient notice that she was harmed* and (2) knowledge or sufficient notice of what the cause of harm was." *Bowen*, 408 Mass. at 205 (emphasis added).

The discovery rule often surfaces in cases involving disease, where a disease or its symptoms may lie latent or undetected after the fact of the defendant's negligent act is first known. E.g., *Olsen v. Bell Tel. Labs., Inc.* 388 Mass. 171, 175 (1983); *Gore v. Daniel O'Connell's Sons, Inc.*, 17 Mass. App. Ct. 645, 647 (1984). " 'Latent [harms] are conditions that are hidden or concealed, and are not discoverable by reasonable and customary observation or

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[16] The critical time may also be characterized as the point when the harm or cause thereof is no longer 'inherently unknowable.' The standards are the same and can be used interchangeably. *Albrecht v. Clifford*, 436 Mass. 706, 714 (2002), quoting *Williams v. Ely*, 423 Mass. 467, 473 n. 7 (1996). See also *Melrose Hous. Auth. v. N.H. Ins. Co.*, 402 Mass. 27 (1988) (discovery rule tolls statute of limitations until the harm and its cause ceases to be inherently unknowable by reasonable inquiry). Indevus emphasizes this language, claiming that if the disease was *"knowable"* then the plaintiffs should have discovered it. See n.19, *infra*, and accompanying text.

inspection.' " *Albrecht v. Clifford*, 436 Mass. 706, 713 (2002), quoting Black's Law Dictionary 429, 887 (7th ed. 1999). For purposes of the statute of limitations, the action accrues when the plaintiff "knew or should reasonably have known that he had contracted [the disease] as a result of conduct of the defendants." *Id.*

The justification for the discovery rule lies in the "unfairness of a rule that holds that the statute of limitations has run even before a plaintiff knew or reasonably should have known that she may have been harmed by the conduct of another." *Id.* "Not only does it offend fairness to require of claimants the gift of prophecy, cf. *Franklin* v. *Albert*, 381 Mass. at 618, but it is unsound judicial policy to encourage the initiation of law suits in anticipation that a grave disease will manifest itself pendente lite." *Gore*, 17 Mass. App. Ct. at 648. At the same time, the rule is limited by it own objective character–*i.e.*, the statute of limitations will only be held in abeyance until the plaintiff *reasonably should discover* the harm. This limitation is premised on the following reasoning:

> A man should not be allowed to close his eyes to facts readily observable by ordinary attention, and maintain for his own advantage the position of ignorance. Such a principle would enable a careless man, and by reason of his carelessness, to extend his right to recover for an indefinite length of time, and thus defeat the very purpose the statute was designed and framed to accomplish.

Melrose Hous. Auth. v. N.H. Ins. Co., 402 Mass. 27, 35 (1988), quoting *Fulcher v. U.S.*, 696 F.2d 1073, 1077 (4th Cir. 1982). Thus, the objective character of the discovery rule strikes a balance between competing concerns–on the one hand it recognizes the unfairness of closing the courthouse doors to a claimant based on facts unknown to her despite reasonable diligence, and, on the other hand, it recognizes that the plaintiff should not be allowed to hide behind her own inexcusable neglect.

4. The Discovery Rule Applied to the Circumstances of This Case

The issue in this case is whether, as of December 11, 1999 (for Count V) and December 11, 2000 for the remaining counts, the plaintiffs knew or should have known that (1) they had VHD, and (2) the cause of that harm was the Diet Drugs.

A. The Arguments of the Parties

Indevus argues that the plaintiffs should have been aware of their condition in the fall of 1997. As a result of intense media coverage in the late summer of 1997, Indevus argues, the plaintiffs were on inquiry notice and should have taken adequate measures to ascertain whether they had been affected by the Diet Drugs. They contend that VHD is not a latent disease–that is, it is detectable, if at all, soon after the ingestion of Redux.[17] The issue of latency is therefore critical to Indevus' argument that the plaintiffs, as a matter of law, reasonably should have discovered their condition shortly after Redux was pulled from the market in the fall of 1997.

The plaintiffs, on the other hand, dispute that they should have discovered their injuries before 2001 or 2002 when they were first diagnosed. First, they argue the issue is not whether VHD is latent *per se*, but whether a reasonable person in their position should have discovered her injury before Dec. 11, 1999. They contend that their actions in attempting to ascertain whether they had been harmed by the Diet Drugs were manifestly reasonable–they did precisely what the FDA, independent medical organizations, and Indevus itself encouraged them to do: consult their physicians. As a result of those examinations and uniformly negative diagnoses,

[17] Although the plaintiffs vigorously dispute this contention, Indevus argues that the plaintiffs are collaterally and judicially estopped from making this argument. See *infra*.

they argue, there was no basis for them reasonably to be expected to know, or even suspect, that they had VHD. Thus, they argue there is, at minimum, a factual issue as to whether they should have known they had VHD and that summary judgment is therefore inappropriate.

B. Analysis of the Parties' Positions

The difference in the parties' positions is how they frame the relevant inquiry. Indevus takes the position that the inquiry is purely objective and to be performed in the abstract–*i.e.*, whether *hypothetically*, a reasonable person should discover VHD if he consulted a physician after exposure to Redux.[18] In Indevus' counsel's own words: "the issue is whether or not it is knowable" or, similarly, "whether or not the injuries were discoverable."[19] Thus, the defendants contend that if plaintiffs' VHD *could have been* discovered in 1997 then the plaintiffs should be charged with knowledge thereof.

The plaintiffs add a more subjective element to the test, asking whether *these plaintiffs* should have known they had VHD, even after consulting physicians who told them they were fine. Under this formulation, the issue of latency is largely irrelevant. Regardless of whether VHD is or is not latent, they argue that it was reasonable under the circumstances for them not to have discovered their injuries.[20]

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[18] In its reply brief, Indevus presents the issue as: "whether there exists any judicially cognizable reason why the doctrine of collateral estoppel does not preclude Plaintiffs from contending that their injuries were inherently unknowable or latent at or about the time they discontinued use of Redux..."

[19] As counsel stated at the hearing held June 16, 2004.

[20] Another Court addressing essentially the same facts adopted a similar position:

> Defendants strongly argue that the MDL litigation has determined that valvular heart disease is not a latent disease and as such the parties in this case are bound by such a finding. The fallacy of Defendant's argument in this regard is that the issue is not whether or not the condition is latent, but

Under Massachusetts law, the plaintiffs' position is correct.[21] Although most of the reported cases discussing the discovery rule deal with the second prong of the inquiry–whether the plaintiff should have discovered *the cause* of the injury, they are nevertheless instructive. Those cases make clear that the objective test must take into account the specific facts and circumstances of the plaintiff and the information known to her. E.g., *Lindsey v. Romano*, 427 Mass. 771, 774 (1998), quoting *McGuinness* v. *Cotter*, 412 Mass. 617, 620 (1992) (" 'In determining whether a party has sufficient notice of causation, our inquiry is whether, *based on the information available to the plaintiff*, a reasonably prudent person *in the plaintiff's position* should have discovered the cause of his or her injuries' " (emphasis added)); *Riley*, 409 Mass. at 245 ("Only if a reasonable person in the plaintiff's position would have been able to discern the harm . . . will the cause of action accrue and the limitations period begin to run... The reasonable person who serves as the standard in this evaluation, however, is not a detached, outside observer assessing the situation without being affected by it"); *Bowen*, 408 Mass. at 208-209 ("whether a reasonable person in the position of the plaintiff would have been on notice . . . depends on the facts"); *Castillo v. Mass. Gen. Hosp.*, 38 Mass. App. Ct. 513, 516 (1995), quoting *Malapanis v. Shirazi*, 21 Mass. App. Ct. 378, 383 (1986) ("a limitations period commences to run when a reasonably prudent person (in the tort claimant's position), reacting to any suspicious circumstances of which he might have been aware . . ., should have discovered that he had been

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> whether... the condition should have been found with 'reasonable diligence.' That is the issue. The issue is not whether or not the condition is latent. Whether Plaintiff should have discovered her condition ... is a fact question.

Dykes v. Reeves, No. 2:03CV121PG at 6-7 (S.D. Miss. Nov. 65, 2003).

[21] Courts analyzing the same issue under other states' discovery rules have come to the opposite conclusion. See, e.g., *French v. Wyeth*, MDL No. 1203, Civil Action No. 03-20206 (E.D. Pa. Feb. 16, 2004).

harmed"). See also *Gore*, 17 Mass. App. Ct. at 647 & n.3 (as a matter of law, plaintiff on notice of cause of injury upon first positive diagnosis linking injury to defendant's conduct); *Zamboni v. Aladan Corp.*, 304 F.Supp.2d 218, 225-26 (D. Mass. 2004) (and cases cited) (where initial diagnosis did not implicate the defendant, knowledge of causation not imputed to plaintiff until subsequent diagnosis implicating the defendant).

Four cases dealing with undiscovered medical conditions are particularly relevant to this case. In *Riley*, the plaintiff had been seeing the defendant psychotherapist who provided drugs and alcohol to the plaintiff and then engaged him in sexual activity. 409 Mass. at 241. This resulted in severe emotional problems to the plaintiff, the source of which he did not realize for several years despite seeing a new psychiatrist. *Id.* at 241-42. The new psychiatrist did not tell the plaintiff that any of his emotional problems were caused by the defendant's conduct. *Id.* at 242. The plaintiff finally realized the source of his emotional problems when the psychiatrist arranged for him to meet with another victim of the defendant. *Id.* at 241-42. The Court disagreed with the defendant's claim that an average reasonable person would have recognized the source of his problems before this time, and emphasized that the standard is not a 'detached' reasonable person, but a "reasonable person *in the position of the plaintiff*." *Id.* at 245 (emphasis added). Thus, the Court held that it was improper to grant summary judgment in the defendant's favor; while the cause of the plaintiff's problems was *knowable,* it was improper to charge the plaintiff with knowledge thereof as a matter of law, before his meeting with the other victim. *Id.*

Also instructive is *Gore v. Daniels O'Connell's Sons, Inc.* In *Gore*, the plaintiff suffered a concussion at work on August 16, 1976 and became deeply depressed and lethargic immediately after the accident. He consulted a series of physicians to help deal with his mental

issues. His initial few neurological examinations revealed no identifiable neurological symptoms that would have linked his emotional problems to his accident. In August, 1977, he was diagnosed with anxiety and depression. Finally, on February 28, 1978, a doctor opined that it was his "impression that the symptoms are related to [Gore's] accident." The Appeals Court affirmed summary judgment against the plaintiff who filed his complaint on April 30, 1981, more than three years after that diagnosis. Somewhat cryptically in a footnote, the Court noted: "The plaintiffs' action was filed April 30, 1981, and, therefore, not within three years of this relatively specific diagnosis. The Lahey Clinic had earlier -- in August, 1977 -- diagnosed Gore's condition as anxiety with depression." The reference to the earlier diagnosis apparently suggests that the limitations period was tolled until the plaintiff–while exercising reasonable diligence–*actually received a positive diagnosis* correlating his disorder to the accident. 17 Mass. App. Ct. at 647 & n.3.

The Supreme Judicial Court's analysis in *Bowen* provides additional guidance. In *Bowen,* the 21 year old plaintiff had surgery to cure vaginal cancer allegedly caused by a drug her mother took during pregnancy. 408 Mass. at 204. She filed suit fourteen years after the surgery. *Id.* The Court held "that the plaintiff had such direct information bearing on the cause of her cancer that the statute of limitations ran before this action was commenced." *Id.* at 208. Specifically, the plaintiff's doctor wrote a letter to the plaintiff and her mother two years after the surgery explaining the recently discovered association between the drug and vaginal cancer in offspring. *Id.* at 209. In addition, the doctor sent a copy of an article published in the *New England Journal of Medicine* detailing those findings. *Id.* Thus, the plaintiffs had been provided with such detailed information that they should have understood both that they had been injured and the

potential cause of that injury. *Id.*

Finally, in *Castillo*, the Appeals Court held that knowledge of technical information in medical records would not be imputed to the plaintiff until an expert later explained the significance of that information to the plaintiff's attorney. 38 Mass. App. Ct. at 516-17. Specifically, a blood test indicating elevated lead levels was performed on the plaintiff in 1981. *Id.* at 514. Those abnormal results were not made known to the plaintiff and the plaintiff was not treated for lead poisoning. *Id.* A subsequent test in 1982 revealed lead poisoning and a suit commenced against the plaintiff's landlord. *Id.* In 1986, during discovery in that case, the plaintiff's attorney obtained the 1981 test results, which were examined and explained by an expert on January 16, 1987. *Id.* As a result, the plaintiff filed suit against the hospital for damages arising from the hospital's failure to inform and treat the plaintiff in 1981. In reversing the allowance of the hospital's motion for summary judgment, the Court held, "we discern no basis for concluding, as matter of law, that a reasonably prudent person in the position of any of the plaintiffs should have discovered, prior to January 16, 1987, that he had been harmed by not having been informed of the 1981 test results." *Id.* at 516. Moreover, the Court held that "[a] determination that receipt of the 1982 blood test results would have aroused the suspicions of that reasonable person sufficiently to spur investigation of the results and implications of the [1981] test and would have led to the discovery that he had been harmed by the failure to inform him of those results, involves a decisional process fraught with resolution of factual issues and, is, therefore, peculiarly within the province of the trier of fact." *Id.* at 516.

These cases illustrate two critical points. First, when a medical condition is at issue, one must evaluate the specific medical, diagnostic or other information *provided to the plaintiff* to

determine whether she should have known of her injury (or its cause). The issue is not whether the condition (or its cause) could have been detected, discovered or diagnosed by an appropriate expert, but whether the plaintiff, in the exercise of reasonable diligence, received "such direct information" that she should have known of her injury and its cause. *Bowen*, 408 Mass. at 208; *Riley*, 409 Mass. at 245; *Castillo*, 38 Mass. App. Ct. at 516; *Gore*, 17 Mass. App. Ct. at 647 & n.3. See also *Zamboni v. Aladan Corp.*, 304 F. Supp.2d 218, 225-26 (D. Mass. 2004) (where doctor initially diagnosed plaintiff's condition as unrelated to defendant's conduct, knowledge of causation not imputed to plaintiff until subsequent correct diagnosis implicating defendant was made); *Harris v. McIntyre*, Civil No. 94-3597-H (Suffolk Superior Ct., June 27, 2000) (Gants, J.) (court must determine what knowledge the plaintiff actually had and when he had it to determine when the plaintiff should have known about the harm). Second, whether a plaintiff exercised reasonable diligence in investigating his/her injuries, and whether, based on the information reasonably available, the plaintiff should have know of the injury typically "involves a decisional process fraught with resolution of factual issues." *Castillo*, 38 Mass. App. Ct. at 516; *Riley*, 409 Mass. at 240.

C. Analysis of the Circumstances of this Case

The plaintiffs have raised, at minimum, a disputed issue of fact as to whether they should have known they had VHD as of December 11, 1999 (for Count V) and December 11, 2000 for the remaining counts. First, a jury could find that the plaintiffs exercised reasonable diligence in discovering their conditions by regularly visiting their physicians. Any argument by Indevus that, as a matter of law, the plaintiffs failed to exercise reasonable diligence in failing to obtain an

echocardiogram is belied by the undisputed evidence in the record that the government, professional cardiac associations, *and the pharmaceutical companies themselves* all instructed that patients merely visit their physicians–not that they routinely obtain an echocardiogram. There was simply not sufficient notice to these plaintiffs, or their physicians for that matter, to say, as a matter of law, that they should have requested and obtained an echocardiogram.[22] In short, a jury could find that these plaintiffs did precisely what other reasonable persons would have done under the circumstances: consult their physicians.

Although the intense media coverage should have put these plaintiffs on notice of the *potential* that they had been harmed by the defendant's conduct, there is nothing in the record which suggests that, as a matter of law, they should have discovered before 2001 or 2002 that they had, in fact, been so harmed. Specifically, based on the summary judgment record before the Court, the first time there was *any indication* of injury conveyed to these plaintiffs was when they received the results of their echocardiograms in 2001 and 2002. Notably, each plaintiff was told during the preceding years that her cardiac examinations were normal. Indeed, Sawyer was told in 1997 that her echocardiogram was normal. Additionally, the plaintiffs suffered no recognizable symptoms which could have put them on notice of cardiac problems. In short, a jury could find that the plaintiffs, after exercising reasonable diligence in routinely visiting their physicians, received no information from which they should have discovered they had been injured by the defendant's conduct. As such, summary judgment must be denied.

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[22] Indeed, in light of the government and professionally endorsed protocols, it is not at all clear that a physician would have indulged such a request by any of the plaintiffs absent some independent indication of cardiac abnormality.

5. Collateral Estoppel, Judicial Estoppel, Latency and the Discovery Rule

Indevus argues that because VHD is not latent and an echocardiogram examination in 1997 should have revealed its presence, as a matter of law, the plaintiffs should have discovered their condition at that time. Although the plaintiffs present evidence that VHD is, in fact, latent, Indevus maintains that they are collaterally and judicially estopped from making this argument as a result of the MDL proceedings.

Indevus' argument fails for two reasons. First, as noted above, the issue of latency is not material to when the plaintiffs should have discovered their condition.[23] Second, even if latency were determinative, this court would not apply the doctrines of collateral or judicial estoppel under the circumstances of this case.

"The judicial doctrine of collateral estoppel provides that '[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.'" *Alba v. Raytheon Co.*, 441 Mass. 836, 841 (2004), quoting *Martin v. Ring*, 401 Mass. 59, 61 (1987). "The purpose of the doctrine is 'to conserve judicial resources, to prevent the unnecessary costs associated with multiple litigation, and to ensure the finality of judgments.'" *Id.* " 'The guiding principle in determining whether to allow defensive use of collateral estoppel is whether the party against whom it is asserted 'lacked full and fair opportunity to litigate the issue in the first action or [whether] other circumstances

[23] There is a critical distinction between latency and progression. Even if VHD was not latent, Indevus does not contest that it is often progressive, such that it may be asymptomatic for a period of time and then emerge in more serious symptomatic forms. Similarly, symptoms may go undetected on auscultation if a follow up echocardiogram is not performed. The relevant point in time is not the point of onset of valvular lesions, but rather the point in time at which the plaintiffs should have been aware they had VHD.

justify affording him an opportunity to relitigate the issue.'" *Id.* at 842.

Before reaching the issue of whether fairness justifies permitting the plaintiffs to litigate the issue of latency, this "court must answer affirmatively four questions: (1) was there a final judgment on the merits in the prior adjudication; (2) was the party against whom estoppel is asserted a party (or in privity with a party) to the prior adjudication; (3) was the issue decided in the prior adjudication identical with the one presented in the action in question; and (4) was the issue decided in the prior adjudication essential to the judgment in the prior adjudication?" *Id.*[24]

This case arguably meets those requirements; collateral estoppel could apply to preclude the plaintiffs' latency arguments. There was a final judgment in *Brown*; the plaintiffs were class members in *Brown*; the issue of latency was concretely decided by Judge Bechtle; and under *Amchem*, this finding was arguably essential to the final judgment. However, as the Supreme Judicial Court noted, the key inquiry is whether the plaintiffs had a full and fair opportunity to litigate the issue or whether other circumstances justify permitting them to litigate it here. *Id.* For the following reasons, this court agrees with the plaintiffs that it would be grossly unfair to preclude them from litigating the issue of latency.[25]

First, as Judge Bechtle recognized, the terms of the Agreement largely marginalized the

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[24] Indevus asserts that the Pennsylvania law of collateral estoppel would govern in the event of a conflict of laws. However, there is no such conflict. Compare *Alba*, 441 Mass. at 841-42, and *City of Pittsburg v. Zoning Bd. of Adjustment*, 559 A.2d 896, 901 (Pa. 1989). Under Pennsylvania law, whether the party against whom collateral estoppel is being asserted had a full and fair opportunity to litigate the issue is considered a fifth formal element. *Id.*

[25] Other courts have concluded that class members are collaterally estopped from challenging Judge Bechtle's latency findings. E.g., *Williams v. Wyeth (In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.)*, MDL No. 1203, Civ. Nos. 03-20244 et al. slip op. at 7-8 (E.D. Pa. Feb. 24, 2004); *Alexander v. Wyeth (In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.)*, MDL No. 1203, Civ. Nos. 03-20206 (E.D. Pa. Jan. 29, 2004). The continuing vitality of those decisions, however, is called into question by a recent decision by the United States Court of Appeals for the Third Circuit. See *In re Diet Drugs*, 369 F.3d 293 (3rd Cir. 2004).

issue of latency.[26] Most notably, the Agreement protected those class members, like the plaintiffs, who were not diagnosed with VHD until January 3, 2003 or whose conditions worsened to symptomatic levels by the year 2015. For those class members, claims asserted against Wyeth through the intermediate or back-end opt-outs were protected against statutes of limitations defenses. Indeed, Judge Bechtle specifically noted that the opt-out provisions adequately safeguarded claims from the very statute of limitations defense asserted here by Indevus. *Brown*, 2000 WL 1222042, at *18 - *19. Thus, because the Agreement was structured to provide sufficient protection against statute of limitations defenses, the class members in the plaintiffs' position lacked a true incentive to fully and vigorously litigate the issue of latency–it simply was not critical to protecting their rights against Wyeth.

On that same score, the evidence presented to this court suggests that class counsel did not, in fact, vigorously litigate this issue. For one, Judge Bechtle noted there was no evidence presented at the fairness hearing indicating that VHD was latent. *Brown*, 2000 WL 1222042, at *47. However, it appears that class counsel possessed such information (Dr. Oury's expert opinion) and simply chose not to present it to that Court. Second, despite the fact that counsel was appointed for all defined "sub-classes," there was no counsel appointed to represent the potential class of Diet Drug users with latent VHD (if any such class existed at all). Accordingly, the interests of this potential sub-class may have gone under-represented, except for the very few objectors who presented *no* scientific evidence to support their latency concerns. Thus, the issue of latency appears, at minimum, not to have been as fully litigated as it could have been.

Additionally, all parties to the Agreement understood that the Agreement or any related

[26] This also indicates that Judge Bechtle's latency finding was not "essential" to the judgment.

findings and statements could not be used beyond enforcing the Agreement itself. There was no reason for any party to anticipate that Judge Bechtle's findings regarding latency would have any preclusive effects at a later time. To the contrary, there were very specific and explicit protections against this. As noted above, Sections VIII.F.3 & VIII.F.4 provided that any findings or statements made in connection with the Agreement could not subsequently be used by either settling party against the other, *or by any third party against either settling party*. Thus, class members would have been justified in expecting that any of Judge Bechtle's findings would have no preclusive effects against them in the future. In sum, where the rights of putative class members with latent or progressive VHD were protected by the Agreement and where they reasonably may have expected any findings regarding latency to have no preclusive effects, there was little, if any, incentive to fully litigate the issue of latency at the fairness hearing.

Finally and most importantly, it would be especially unfair to preclude the plaintiffs from arguing latency in light of the notice they were given regarding the non-preclusive effects of the Agreement. As the Third Circuit Court of Appeals noted:

> The average class member has had no hand in negotiating the terms of the settlement. . . . As in *Georgine v. Amchem Prods.*, the individual class members here have claims "that frequently receive huge awards in the tort system." 83 F.3d at 633. They can hardly knowingly waive some of their tort rights without a clear notice of what they are waiving. They may be entirely dependent on the class notice for this information. . . . *It follows that the preclusion language in the Diet Drugs class notice and settlement agreement must, in order to avoid due process concerns, be strictly construed against those who seek to restrict class members from pursuing individual claims.*

In re Diet Drugs, 369 F.3d at 308 (emphasis added). Here, Class members were explicitly told that their rights "to pursue legal claims against Non-Settling Defendants is not affected by this Settlement Agreement..." Thus, class members were justified in believing that there was no risk

of adverse findings by Judge Bechtle carrying preclusive effects against non-settling defendants like Indevus. Even if class counsel conceded latency for purposes of getting the Agreement approved, it would be grossly unfair to bind unwitting class members to that concession because they were explicitly and unequivocally told that those proceedings would not affect their rights against non-settling parties.

For similar reasons of fairness, this court would not invoke the doctrine of judicial estoppel to preclude the plaintiffs' latency arguments. The doctrine of judicial estoppel "precludes a party in certain circumstances from asserting a position in one proceeding that is contrary to a position that the party previously asserted successfully in another proceeding." *E. Cambridge Sav. Bank v. Wheeler*, 422 Mass. 621, 621 (1996). The precise circumstances when the doctrine applies have not been clearly defined. *Tinkham v. Jenny Craig, Inc.*, 45 Mass. App. Ct. 567, 574 (1998). However, the primary purpose of the doctrine is to prevent litigants from playing "fast and loose" with the courts–*i.e.*, using "intentional self-contradiction . . . as a means of obtaining unfair advantage in a forum for suitors seeking justice." *Patriot Cinemas, Inc. v. General Cinema Corp.*, 834 F.2d 208, 212 (1st Cir. 1987). Thus, the key factor in whether to apply judicial estoppel is "whether [the] party is seeking to use the judicial process in an inconsistent way that courts should not tolerate." *E. Cambridge Sav. Bank*, 422 Mass. at 623; *Correia v. DeSimone*, 34 Mass. App. Ct. 601, 604 (1993) (primary function of judicial estoppel is to protect integrity of the courts).

As the above discussion makes clear, these plaintiffs are not playing "fast and loose" with the courts and are not abusing the judicial process. The Third Circuit's observation that "the average class member has had no hand in negotiating the terms of the settlement" is particularly

relevant here. *In re Diet Drugs*, 369 F.3d at 308. Whatever position class counsel took at the fairness hearing,[27] it would be inappropriate to charge the current plaintiffs with abusing the judicial process when they had essentially no involvement in the earlier proceeding. The plaintiffs are not using "intentional self-contradiction" to gain an unfair advantage in the courts. In addition, the "objectors" to the Agreement argued that VHD was latent. Thus, the plaintiffs' current position on latency is, in fact, consistent with the one asserted by the objectors (who could be said to have represented the current plaintiffs at the fairness hearing) and the doctrine of judicial estoppel is therefore inapposite.

Therefore, even if this court were to adopt Indevus' understanding of the discovery rule in which latency is a material issue, there would still be a genuine dispute of fact as to whether VHD is a latent condition. Namely, the plaintiffs submit the affidavits of Dr. George Massing, M.D. and Dr. James Oury, M.D., who both opine that VHD is a latent condition. This court would not preclude those opinions and would permit the plaintiffs to argue latency. For these additional reasons, summary judgment must be denied.

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[27] Although it appears from the decision in *Brown* that all of the experts, including those proffered by class counsel, testified that VHD is not latent, it does not necessarily follow that class counsel definitively adopted this position. As noted above, class counsel's brief in support of the settlement explicitly recognized that the rights of class members whose conditions worsened over time or were not detected until 2003 were protected by the Agreement.

ORDER

For the reasons stated above, it is hereby **ORDERED** that the defendant's Motion for Summary Judgment is **DENIED**.

DATED: July 21, 2004

Raymond J. Brassard
Justice of the Superior Court

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